GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1520
ANSWERED ON:29.10.2008
GRANT OF PERMISSION TO MNCS FOR CLINICAL TRIALS
Malhotra Prof. Vijay Kumar;Rijiju Shri Kiren

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to grant permission to the foreign pharmaceutical companies to conduct clinical trials in the country;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Government has received complaints that the pharmaceutical companies do not adhere to the laid down rules pertaining to clinical tests; and

(d) if so, the details thereof alongwith the action taken by the Government thereon?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b) Permission to conduct clinical trials is granted to foreign as well as domestic pharmaceutical companies Schedule Y (amended in 2005) of Drug and Cosmetics Rules 1945 specifies the guidelines and requirements for conducting clinical trial in the country. This is applicable for both foreign as well as domestic pharmaceutical companies for clinical trial in India. As per the said Schedule, it is also mandatory to conduct clinical trial as per Good Clinical Practice (GCP) guidelines (2001) published by Government of India. Application for clinical trial is requested to be submitted in Form-44 alongwith prescribed fees and chemical & pharmaceutical information, animal & pharmacological, toxicological data, human clinical data of safety and efficacy etc.

(c) No such complaint that the pharmaceutical companies do not adhere to the laid down rules pertaining to clinical tests has been received by the Drugs Controller General (India).

(d) Does not arise.